

DOCKET NUMBER  
PROPOSED RULEMAKING 35  
(68 FR 68549)

12

## Certification Board of Nuclear Cardiology

9929 Main Street Suite C Damascus, MD 20872 Phone: (301) 253-7122 Fax: (301) 253-7123  
E-mail: cbnc@starpower.net Internet webpage: www.cbnc.org

DOCKETED  
USNRC

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February 18, 2004

February 19, 2004 (2:27PM)

Secretary  
U.S. Nuclear Regulatory Commission  
11555 Rockville Pike  
Rockville, MD 20852

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

RE: RIN 3150-AH19

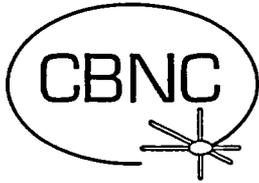
Dear Mr. Secretary:

The Certification Board of Nuclear Cardiology (CBNC) submits the following comments in response to the *Federal Register* notice of December 9, 2003 soliciting comments relative to "Medical Use of Byproduct Material – Recognition of Specialty Boards."

1. It should be noted that, if changes to the current Training and Experience requirements are made as outlined in the December 9, 2003 *Federal Register* notice and a Final Regulation is published in perhaps September 2004, the currently approved Boards, including ours, would have less than 60 days to make application, time for application processing including review by the ACMUI, final approval by NRC staff and notification to applicant boards before the current "transition period" ends on October 24, 2004. We believe this deadline must be extended if NRC proceeds with the proposed changes to the current 10 CFR Part 35 T & E requirements.
2. The CBNC believes that Agreement States can and should meet the October 24, 2005 deadline for developing a compatible rule. Already we have seen much confusion and misunderstanding on the part of applicants seeking AU status as they have one [or more] set of requirements in Agreement States and another set in Non-Agreement States. In some states these changes will require legislative action and the process needs to be started immediately in order to achieve compliance with the federal mandate. Extending the deadline is quite unreasonable and unnecessary in our opinion and we oppose such a delay in final implementation.

Template = SECY-067

SECY-02



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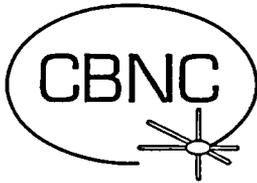
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William D. Nelligan III, CAE  
*Executive Director*

Dawn M. Edgerton  
*Executive Director Designee*

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3. We agree with the ACMUI recommendation that "the requirements for work experience for authorized users in Parts 35.190, 35.290, and 35.390 be changed to require experience with performing quality control check of instruments rather than with calibrating instruments."
4. Relative to the language in the Preceptor Letter, we recommend that the preceptor "attest to the candidate's knowledge and ability to handle radioisotopes in preserving the health and safety of the patient and the provider." We are in agreement that the preceptor should not be required to attest to the general clinical competency of the candidate.
5. In response to NRC's invitation to comment on the use of the word "attestation" rather than "certification" in preceptor statements, we clearly favor the word "attestation". The word "certification" should be reserved as reference to those individuals who are certified by one of the NRC recognized boards.
6. Relative to NRC's Invitation for Public Comment on Specific Issues:
  - a. If the proposed revisions for T & E are adopted, we believe that AUs will have adequate training in radiation safety.
  - b. As stated above, we favor the use of the word "attestation" rather than "certification" in preceptor statements.
7. In Section 35.14 – Notifications, the added requirement to paragraph (a) should call for "written attestation" not "written certification".



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### PAGE THREE

8. Relative to amendments to Section 35.290, we strongly support posting the approved and recognized specialty boards on the NRC's Web page.
9. We agree that the proposed revisions be a matter of compatibility between NRC and the Agreement States just as is true in the current regulations pertaining to T & E.

The Certification Board of Nuclear Cardiology appreciates this opportunity to comment on the proposed amendments to NRC's regulations governing the medical use of byproduct material. We would welcome the opportunity to discuss in detail any of our comments with staff or Commissioners.

Sincerely,

  
James E. Udelson, M.D., Vice President  
Certification Board of Nuclear Cardiology